

CLAIMS (modified in response to EPO notification of 19/06/2001)

1. Bacterium *Tropheryma whippelii* responsible for Whipple's disease, isolated and established in culture.
- 5 2. Bacterium according to claim 1 obtained from a culture of human fibroblasts after at least 2 months of incubation in a culture medium based on MEM.
- 10 3. Bacterium according to claim 1 or 2, characterized in that it is deposited in the CNCM of the Institut Pasteur under the number I-2202.
4. Antigen of a bacterium according to one of claims 1 to 3.
- 15 5. Antigen according to claim 4, characterized in that it is a protein selected from those with molecular weights of about 35, 50, 60, 100 and 200 kD determined in Figures 2 and 3 by polyacrylamide gel electrophoresis using the Western blotting technique.
- 20 6. Specific antibody directed against the bacterium or an antigen of the bacterium according to one of claims 1 to 5.
7. Antibody according to claim 6, characterized in that it is a polyclonal antibody of animal origin, preferably a mouse immunoglobulin.
- 25 8. Antibody according to claim 6, characterized in that it is a monoclonal antibody.
9. Antibody according to claim 8, characterized in that it is a monoclonal antibody produced by a hybridoma deposited in the CNCM of the Institut Pasteur under the registration number I-2411.
- 30 10. Antigen according to claim 5, characterized in that it is a protein of 200 kD which reacts with an antibody according to claim 9.

11. Use of a bacterium according to any one of claims 1 to 3 or an antigen according to claim 4, 5 or 10 for the *in vitro* diagnosis of diseases associated with infections caused by the bacterium *Tropheryma whippelii*.
- 5 12. Use of an antibody according to one of claims 6 to 9 for *in vitro* diagnosis of the disease associated with infections caused by *Tropheryma whippelii* bacteria.
- 10 13. Method for the *in vitro* serological diagnosis of Whipple's disease, comprising the steps which consist essentially in detecting an immunological reaction between an antibody specific for the bacterium according to one of claims 6 to 9 and an antigen of said bacterium according to one of claims 4, 5 and 10.
- A 15 14. Method for the *in vitro* serological diagnosis of Whipple's disease, comprising the step which consists essentially in detecting an immunological reaction between an antibody specific for a human immunoglobulin which recognizes said bacterium according to one of claims 1 to 3 and a said human immunoglobulin which recognizes said bacterium according to claims 1 to 5.
- 20 15. Method of serological diagnosis according to claim 14 comprising the following steps:
- 25 - depositing a solution containing the bacterium as defined in claims 1 to 3, in or on a solid support;
- introducing the test serum or biological fluid into or onto said support;
- 30 - introducing a solution of a labeled antibody specific for a human immunoglobulin which recognizes said bacterium, into or onto the support;
- observing an incubation period;

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- rinsing the solid support; and
 - detecting said immunological reaction.

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16. Kit for the *in vitro* detection of Whipple's disease by the method of one of claims 13 to 15, essentially comprising the following components:
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- a solution containing the bacterium or an antigen as defined in claims 1 to 5 and 10; and/or
 - a solution containing at least one antibody according to one of claims 6 to 9; and/or
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- a solution containing at least one antibody specific for a human immunoglobulin which recognizes said bacterium according to claims 1 to 3.
17. Kit according to claim 16, characterized in that it comprises at least one labeled specific antibody.
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18. Fragment of the *rpoB* gene of the bacterium *Tropheryma whippelii* according to one of claims 1 to 3, characterized in that it comprises the nucleotide sequence SEQ ID N° 3.
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19. Oligonucleotide comprising a sequence specific for the *rpoB* gene of the bacterium *Tropheryma whippelii* according to one of claims 1 to 3, said specific sequence comprising at least 12 consecutive nucleotide units included in the sequence SEQ ID N° 3.
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20. Single-stranded oligonucleotide according to claim 19 selected from oligonucleotides having a sequence of at least 12 consecutive nucleotide units included in one of the sequences to SEQ ID N° 4 and 5, and from the oligonucleotides complementary to these oligonucleotides.

21. Oligonucleotide according to claim 19 or 20, characterized in that it consists of the sequences SEQ ID N° 4 and 5.
22. Probe for detecting *Tropheryma whippelii* bacteria in a biological sample, characterized in that it comprises a sequence according to claim 18 or an oligonucleotide according to one of claims 19 to 21.
23. Process for determining the presence or absence of a *Tropheryma whippelii* bacterium in a sample which contains or may contain nucleic acids of at least one such bacterium, characterized in that said sample is brought into contact with at least one probe ... claim 22 and the formation or absence of formation of a hybridization complex between said probe and the nucleic acid of the sample is then determined.
24. Nucleotide primer which can be used for synthesizing the *rpoB* gene of *Tropheryma whippelii* in the presence of a polymerase, characterized in that it comprises an oligonucleotide according to claims 19 to 21, preferably an oligonucleotide comprising one of the sequences SEQ ID N° 4 and SEQ ID N° 5.